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10/517,908	01/30/2006	Akio Wakabayashi	AKIOWAK.006NP	6878

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EXAMINER

ANDERSON, MICHAEL J

ART UNIT	PAPER NUMBER
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3767

NOTIFICATION DATE	DELIVERY MODE
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12/26/2008

ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary	Application No. 10/517,908	Applicant(s) WAKABAYASHI, AKIO	
	Examiner MICHAEL J. ANDERSON	Art Unit 3767	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 13 October 2008.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-5, 7-22 and 24-31 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-5, 7-22 and 24-31 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 09 December 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-4, 7 rejected under 35 U.S.C. 102(b) as being anticipated by Boudreault (US Patent No. 5,186,714) (Hereinafter, Boudreault).

With regards to claim 1 Boudreault discloses (abstract, figures 1-4) a drainage device for draining unwanted matter from a body cavity of an animal, the drainage device comprising: a tube having first and second ends, said first end adapted to connect to a vacuum source of at least approximately 125 torr (column 5, line 4), said second end adapted to be inserted into a body cavity of an animal; and a plurality of holes formed into the wall of an insertion portion of said tube, said insertion portion of said tube configured to be inserted into said body cavity of said animal, each of said plurality of holes communicating a respective suction force from an inner bore of said tube to matter outside said tube, the area of each of said plurality of holes selected such that each of said respective suction forces is insufficient to cause injury to proximate body tissues within said body cavity of said animal.

With regards to claim 2 Boudreault discloses (abstract, figures 1-4) the drainage device as described in claim 1, and further discloses wherein said animal is a human.

With regards to claim 3 Boudreault discloses (abstract, figures 1-4) the drainage device as described in claim 1, and further discloses wherein said body cavity is a chest cavity.

With regards to claim 4 Boudreault discloses (abstract, figures 1-4) the drainage device as described in claim 1, and further discloses wherein a thickness of the wall of said tube is selected to maintain the structural integrity of said tube when said first end of said tube is connected to a vacuum source of approximately ~~[[100]]~~200 torr or greater (column 5, line 4).

With regards to claim 7 Boudreault discloses (abstract, figures 1-4) the drainage device as described in claim 1, and further discloses wherein each hole is approximately circular and has a diameter no greater than around one half of an internal diameter of said tube (figure 1).

With regards to claim 13 Boudreault discloses (abstract, figures 1-4) the drainage device as described in claim 1, and further discloses it further comprising: a vacuum chamber, said vacuum chamber having a gas outlet port adapted to be connected to a vacuum source of at least about ~~[[50]]~~125 torr, said vacuum chamber having an inlet port connected to said first end of said tube, said inlet port communicating a suction force from said gas outlet port to said first end of said tube, said vacuum chamber having a fluid drainage outlet port through which fluid matter from said body cavity flows in a direction away from said body cavity.

With regards to claim 14 Boudreault discloses (abstract, figures 1-4) the drainage device as described in claim 13, and further discloses further comprising: a vacuum

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relief valve included in said vacuum chamber, said vacuum relief valve opening to direct atmospheric air into said vacuum chamber when a vacuum pressure inside said vacuum chamber exceeds a predetermined threshold.

With regards to claim 15 Boudreault discloses (abstract, figures 1-4) discloses a high vacuum pressure body cavity drainage system, comprising: a vacuum source of approximately $[[50]]125$ torr or greater; and a tube having first and second ends, said first end of said tube adapted to be connected to said vacuum source, said tube having side holes in the wall of an insertion portion of said tube, said insertion portion of said tube configured to be inserted into a body cavity of an animal, each of said side holes conveying a respective suction force from an inner bore of said tube to matter outside said tube, the area of each of said side holes selected such that said respective suction force conveyed by each of said holes is insufficient to cause injury to living tissue in said body cavity, wherein the suction force conveyed at any of the side holes is less than capillary pressure in the animal each hole has an area no greater than that of a circle having a diameter of around one half of an internal diameter of said tube.

With regards to claim 16 Boudreault discloses (abstract, figures 1-4) the high vacuum pressure body cavity drainage system described in claim 15, and further discloses it further comprising: a one-way valve maintaining unidirectional flow of gas and fluid from said body cavity toward said vacuum source, said one-way valve located between said insertion portion of said tube and said vacuum source, said one-way valve configured to maintain such unidirectional flow when said vacuum source is around $[[50]] 125$ torr or more.

With regards to claim 17 Boudreault discloses (abstract, figures 1-4) the high vacuum pressure body cavity drainage system described in claim 15, and further discloses it further comprising: a vacuum relief valve having an atmosphere side and a vacuum side, said vacuum relief valve opening to admit atmospheric air through said vacuum relief valve when a vacuum pressure on said vacuum side of said vacuum relief valve exceeds a predetermined threshold, said vacuum relief valve located between said insertion portion of said tube and said vacuum source.

With regards to claim 18 Boudreault discloses (abstract, figures 1-4) the high vacuum pressure body cavity drainage system described in claim 15, and further discloses it, further comprising: a vacuum chamber located between said insertion portion of said tube and said vacuum source, said vacuum chamber substantially separating fluid matter drained from said body cavity from gaseous matter drained from said body cavity.

With regards to claim 19 Boudreault discloses (abstract, figures 1-4) the high vacuum pressure body cavity drainage system described in claim 15, and further discloses wherein said vacuum source is of approximately [[100]]200 torr or greater.

With regards to claim 20 Boudreault discloses (abstract, figures 1-4) the highly efficient body cavity drainage system, comprising: a vacuum source of approximately [[50]] 125 torr or greater; and a tube having a vacuum end and an insertion end, said vacuum end of said tube adapted to receive a vacuum force, said tube having sufficient structural strength to avoid collapse when said vacuum force is applied to said vacuum end, said tube having side holes in the wall of an insertion portion of said tube near said

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insertion end, said insertion portion of said tube configured to be inserted into a body cavity of an animal, each of said side holes directing a respective suction force from a space inside said tube to a space outside said tube, the area of each of said side holes selected such that said respective suction force directed by each of said holes is insufficient to cause injury to the portions of the body of said animal exposed in said body cavity, a connector having a drainage tube end and a vacuum end, said connector having a one-way valve permitting a flow of fluid or gas from said drainage tube end toward said vacuum end of said connector, said one-way valve substantially restricting a flow of fluid or gas from said vacuum end of said connector toward said drainage tube end, said drainage tube end coupled to said vacuum end of said tube, said vacuum end of said connector adapted to receive a vacuum force; and a vacuum chamber, said vacuum chamber having a gas outlet port coupled to said vacuum source, said vacuum chamber having an inlet port coupled to said vacuum end of said connector, said inlet port communicating a vacuum force from said gas outlet port to said vacuum end of said connector, said vacuum chamber having a fluid drainage outlet port through which fluid matter from said body cavity flows in a direction away from said body cavity.

With regards to claim 21 Boudreault discloses (abstract, figures 1-4) the highly efficient body cavity drainage system described in claim 20, and further discloses it further comprising: a vacuum relief valve in said vacuum chamber, said vacuum relief valve having an atmosphere side and a vacuum side, said vacuum relief valve opening to admit atmospheric air through said vacuum relief valve when a vacuum pressure on said vacuum side of said vacuum relief valve exceeds a predetermined threshold.

With regards to claim 22 Boudreault discloses (abstract, figures 1-4) the highly efficient body cavity drainage system described in claim 20, and further discloses wherein said vacuum source is of approximately ~~[[100]]~~200 torr or greater.

With regards to claim 26 Boudreault discloses (abstract, figures 1-4) the high vacuum pressure, high efficiency body cavity drainage system, comprising: means for receiving a vacuum source of approximately ~~[[50]]~~ 125 torr or greater; means for distributing and applying said vacuum source to a multiplicity of locations within a body cavity of an animal; and means for regulating the respective suction force applied at each of said multiplicity of locations such that each of said respective suction forces is incapable of injuring bodily tissue exposed within said body cavity.

With regards to claim 27 Boudreault discloses (abstract, figures 1-4) the high vacuum pressure, high efficiency body cavity drainage system described in claim 26, and further discloses it further comprising: means for maintaining a unidirectional flow of fluids and gas drained from said body cavity in a direction away from said body cavity.

With regards to claim 28 Boudreault discloses (abstract, figures 1-4) the high vacuum pressure, high efficiency body cavity drainage system described in claim 26, and further discloses it further comprising: means for maintaining vacuum pressure in said high pressure, high efficiency body cavity drainage system at a predetermined level by allowing atmospheric air to enter said drainage system when said vacuum pressure in said drainage system exceeds said predetermined level.

With regards to claim 29 Boudreault discloses (abstract, figures 1-4) the high vacuum pressure, high efficiency body cavity drainage system described in claim 26,

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and further discloses it further comprising: means for separating fluids drained from said body cavity from gases drained from said body cavity.

With regards to claim 30 Boudreault discloses (abstract, figures 1-4) the drainage device as described in claim 1, wherein each hole has an area no greater than that of a circle having a diameter of around one half of an internal diameter of said tube.

With regards to claim 31 Boudreault discloses (abstract, figures 1-4) the highly efficient body cavity drainage system described in claim 20, wherein the largest area of any of said side holes is approximately that of a circle having a diameter of less than one half the internal diameter of said tube.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 5, 8-12 and 24-25 rejected under 35 U.S.C. 103(a) as being unpatentable over Boudreault (US Patent No. 5,186,714) (Hereinafter, Boudreault) in view of Atckley (US Patent No. 4,451,257) (Hereinafter, Atckley) and/or Rosenberg (US Patent No. 5,100,395) (Hereinafter, Rosenberg).

With regards to claims 5, 8-10, 12 and 24-25 Boudreault discloses (abstract, figures 1-4) the drainage device as described in claim 4, however Boudreault does not disclose wherein least 100 holes are formed into the wall of said tube or the size of the holes or tube with a valve. Both Atckley (1-34) and Rosenberg (figure 1-7) disclose a drainage device wherein at least 100 holes are formed into the wall of said tube and the holes and tube having various sizes with a valve. Therefore, it would have been obvious to a person of ordinary skill in the art at the time the invention was made to modify the drainage device of Boudreault with the number and size of the holes of Atckley or Rosenberg to prevent clogging or tissue damage.

Response to Amendment

The present communication responds to the Amendment of 10/13/2008. By this communication, no claims were amended. The amendments did not add new matter. Claims 1-5, 7-22 and 24-31 are pending. The rejection(s) are as stated.

Response to Arguments

Applicant's arguments filed 10/13/2008 have been fully considered but they are not persuasive. With regards to Boudreault disclosure lacking the proper units of pressure and disclosing only "-500 Hg" leaving out the commonly used length measures

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such as inches, cm or mm, regardless of which commonly used length unit of measure chosen to fill this gap the vacuum pressure -500 inchesHg, cmHg, or mmHg is still greater than 125 torr. With regards to the rejection of claim 20, claim 20 was misnumbered claim 16 in the previous office action.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to **MICHAEL J. ANDERSON** whose telephone number is (571)272-2764. The examiner can normally be reached on M-F 6:30 am to 3:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kevin C. Sirmons can be reached on (571) 272-4965. The fax phone

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number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Michael J Anderson
Examiner
Art Unit 3767

MJA
12/21/2008

/Nicholas D Lucchesi/
Supervisory Patent Examiner, Art Unit 3763